CC Ethics Grand Rounds

- December 6th: How should clinicians handle apparently inappropriate surrogates?
- February 7th: Informing estranged family members of genetic risks.
- April 4th: Is it ethical to treat dead patients?

Ethics Grand Rounds

Pregnancy risks and contraception wording in consent forms

Barry Anderson, M.D.
CTEP

Cooperative Studies

- NCI cooperative studies include numerous institutions around the country in the same study of new treatments for cancer.
- Institutions involved in these studies are not able to amend the protocol itself, but sometimes can change the consent language.

Pregnancy Risks

- To minimize risks, chemotherapy treatment studies specify in the consent form that women of child bearing potential must abstain from heterosexual intercourse, or use effective contraception.
- Consent forms typically list which forms of contraception are considered sufficiently effective.

Concern

- One institution wished to participate in NCI cooperative chemotherapy studies.
- However, the institution operates under a directive which forbids promoting or condoning contraception, including in research consent forms.

Bioethics Consult

- The institution contacted the NCI and asked whether it could participate in cooperative studies, but delete mention of contraception from its consent forms.
- The NCI contacted the bioethics department for input.

Possible Exclusion

- In the view of the consultants, individuals and individual institutions do not have a right to participate in research studies.
- Thus, the NCI could decide to exclude institutions that do not agree to use mandated language in consent forms.

Increasing Access

- At the same time, including the institution would allow more women access to NCI treatment trials
- Thus, the consultants thought NCI should include the institution if it could so without increasing the risks, or undermining the value or validity of the study.

No Consent Language

- The consultants discussed the possibility of leaving mention of contraception out of the consent form, but having the investigators convey this information verbally.
- It was felt that this approach likely would be unacceptable to the institution.

Focus on Pregnancy

- A second possibility considered was to state explicitly that women must not get pregnant while on the study and leave the details up to the individual women.
- Concern was expressed that some women may have inaccurate views regarding which methods effectively minimize the risks of pregnancy.

Level of Evidence

- The consultants also discussed whether the approach taken might differ depending upon whether the drug under study was known to cause birth defects, or there simply was no data on whether the drug causes birth defects.